

CLAIM LISTING

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Presently amended) A method of eliminating or reducing ~~infection~~ greater than about 75% of infectious agent binding sites present in a biological material, the method comprising:
 - (a) ~~removing a binding site~~ washing said biological material two or more times with an aliquot of a preparation until greater than about 75% of said binding sites are removed ~~contained in~~ from the material;
 - (b) separating said aliquot from said biological material after each washing; and
 - (c) determining the amount of said binding sites in said separated aliquot, whereby said ~~so that an~~ infectious agent is prevented or inhibited from binding to the biological material, wherein the method maintains the structural integrity of the biological material.
2. (Original) The method of claim 1, wherein the infection is prion infection, and the infectious agent is prion protein.
3. (Original) The method of claim 1, wherein the biological material is bioprosthetic tissue.
4. (Original) The method of claim 3, wherein the structural integrity of the tissue is maintained.
5. (Presently amended) The method of claim 3, ~~further comprising contacting the bioprosthetic tissue with a preparation comprising~~ wherein said preparation comprises a surfactant.
6. (Presently amended) The method of claim 3, ~~further comprising contacting the bioprosthetic tissue with a preparation comprising~~ wherein said preparation comprises a surfactant and a denaturing agent.
7. (Original) The method of claim 6, wherein the surfactant is Tween 80.
8. (Original) The method of claim 6, wherein the denaturing agent is a protic solvent.
9. (Original) The method of claim 8, wherein the protic solvent is an alcohol.
10. (Original) The method of claim 9, wherein the alcohol is ethanol or isopropanol.
11. (Presently amended) The method of claim 6, wherein the preparation further comprises [[an]] a cross linking agent.

12. (Original) The method of claim 11, wherein the cross linking agent is an aldehyde.
13. (Original) The method of claim 12, wherein the aldehyde is formaldehyde or glutaraldehyde.
14. (Presently amended) The method of claim 1, wherein the infectious agent binding site is comprised of a phospholipid.
15. (Original) The method of claim 14, wherein the phospholipid is selected from the group consisting of phosphatidylinositol, phosphatidylethanolamine, gangliotetraosylceramide, phosphatidylserine, phosphatidylcholine, phosphatidic acid, and sphingomyeline.
16. (Original) The method of claim 14, further comprising contacting the tissue with a preparation including a phospholipase.
17. (Presently amended) The method of claim 1, ~~further comprising contacting the bioprosthetic tissue with a~~ wherein said preparation comprises formaldehyde, ethanol, and Tween 80.
18. (Original) The method of claim 2, wherein the prion protein further comprises prion-precursor protein.
19. (Original) The method of claim 1, further comprising a terminal sterilization step.
20. (Presently amended) The method of claim [[1]] 2, further comprising washing the tissue to promote removal of the prion protein.
21. (Presently amended) A method of ~~treating~~ removing a binding site for an unwanted protein from a biological material, the method comprising:
(a) washing the biological material two or more times with an aliquot of a preparation in an amount effective to remove greater than about 75% of said binding sites removing a binding site contained in the material, wherein each washing step uses a fresh aliquot of said preparation;
(b) separating said aliquot from said biological material; and
(c) determining the amount of said binding site in said separated aliquot, whereby said so that an unwanted protein is prevented or inhibited from binding to the biological material, wherein the method maintains the structural integrity of the biological material.
22. (Original) The method of claim 21, wherein the unwanted protein is selected from the group comprising alkaline phosphatase, Thy-1, and acetylcholinesterase.

23. (Presently amended) A method of eliminating or reducing ~~infection~~ greater than about 75% of infectious agent binding sites present in a biological material, said binding site being a protein or polysaccharide, the method comprising: ~~removing a binding site comprising a protein or polysaccharide, contained in the material~~
(a) washing said biological material two or more times with an aliquot of a preparation until greater than about 75% of said binding sites are removed from said material, wherein each contact step uses a fresh aliquot of said preparation;
(b) separating said aliquot from said biological material; and
(c) determining the amount of said protein or polysaccharide binding site in said separated aliquot, whereby said ~~so that an~~ infectious agent is prevented or inhibited from binding to the biological material, wherein the method maintains the structural integrity of the biological material.
24. (Original) The method of claim 23, wherein the infection is prion infection, and the infectious agent is prion protein.
25. (Cancelled) The method of claim 23, wherein the structural integrity of the tissue is maintained.
26. (Cancelled) The method of claim 23, further comprising contacting the bioprosthetic tissue with a preparation comprising an enzyme that digests the binding site.
27. (Cancelled) The method of claim 26, wherein the preparation comprises heparinase, in an amount effective to remove the binding site.
28. (Presently amended) The method of claim 23, ~~further comprising contacting the bioprosthetic tissue with a preparation comprising~~ wherein said preparation comprises a solvent, a surfactant, or a chaotropic agent in an amount effective to extract the binding site from the ~~tissue~~ biological material.
29. (Cancelled) The method of claim 23, further comprising contacting the bioprosthetic tissue with a preparation that chemically derivatizes a polycationic site, thereby eliminating the binding site from the tissue.
30. (Cancelled) The method of claim 23, wherein the binding sites has binding affinity to exogenous prion protein.
31. (Cancelled) The method of claim 23, further comprising contacting the tissue with a preparation that has binding affinity for endogenous prion protein, so that a bound complex is formed between the preparation and the endogenous prion protein.

32. (Cancelled) The method of claim 31, further comprising a washing step to remove the bound complex from the tissue.
33. (Cancelled) A method of eliminating or reducing infection in a bioprosthetic tissue, the method comprising blocking a binding site contained in the tissue so that an infectious agent is prevented or inhibited from binding to the binding site.
34. (Cancelled) The method of claim 33, wherein the infection of prion infection, and the infectious agent is prion protein.
35. (Cancelled) The method of claim 33, wherein the structural integrity of the tissue is maintained.
36. (Cancelled) The method of claim 33, wherein the blocking step further comprises contacting the bioprosthetic tissue with a preparation comprising one or more polysulfonated polyglycosides.
37. (Cancelled) The method of claim 36, wherein the one or more polysulfonated polyglycosides are selected from a group consisting of pentosan polysulfate, sulfated colomycin, dextran sulfate, sulfated carageenans, and heparin/heparan sulfate. 4
38. (Cancelled) The method of claim 36, wherein the contacting step is performed at a temperature of about 37 °C.
39. (Cancelled) The method of claim 33, wherein the contacting step promotes the dissociation of prion protein from the bioprosthetic tissue.
40. (Cancelled) A method of eliminating or reducing infection in a bioprosthetic tissue, the method comprising blocking an infectious agent so that the infectious agent is prevented or inhibited from binding to a binding site in the tissue.
41. (Cancelled) The method of claim 40, wherein the infection is prion infection, and the infectious agent is prion protein.
42. (Cancelled) The method of claim 40, wherein the blocking step further comprises contacting the bioprosthetic tissue with a preparation comprising tetrasubstituted porphorins, polyanionic fungal agents, congo red, fast red, or trypan red.
43. (Cancelled) The method of claim 40, wherein the method is performed before, during, or after fixation.
44. (Cancelled) The method of claim 40, wherein the method is performed during bioburden reduction.
45. (Cancelled) The method of claim 40, wherein the method is performed during final sterilization.

46. (Cancelled) The method of claim 40, wherein the method is performed during packaging.
47. (Cancelled) The method of claim 46, further comprising storing the tissue in the preparation.
48. (Cancelled) The method of claim 42, wherein the preparation further comprises one or more cross-linkable groups that prevent or inhibit dissociation of the one or more polysulfonated polyglycosides.
49. (Cancelled) The method of claim 48, wherein the cross-linkable group is selected from a group consisting of lysine groups and azide moieties.
50. (New) The method of claim 1, wherein 98% of the binding sites are removed from the biological material.
51. (New) The method of claim 21, wherein 98% of the binding sites are removed from the biological material.
52. (New) The method of claim 23, wherein 98% of the binding sites are removed from the biological material.
53. (New) The method of claim 1, wherein each washing step uses a fresh aliquot of said preparation